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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,898	04/15/2004	Paul D. Ziegler	P-11173.00	7576

27581 7590 10/11/2005

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Tata

Office Action Summary	Application No.	Applicant(s)	
	10/824,898	ZIEGLER ET AL.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03142005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 3/14/2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because one of the references is lacking a publication date. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

`Arrangement of the Specification`

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)),

and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

It is suggested that the headings not be underlined or bolded.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if the medium, instructions, or both are being claimed. Apparatus claims cannot solely claim instructions. It is suggested to first positively recite the medium.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1- 5, 7, 9-15, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bornzin et al. (5,549,650).

6. In regards to claims 1, 10, and 11, therapy is delivered at a first rate (Fig. 10, 860) while a parameter is monitored (Fig. 10, 862), and it is determined whether the therapy was delivered for a predetermined portion of the first time period (Fig. 10, 862). This is repeated for a next rate over a next time period (Fig. 10, 874 to 876 to 878 to 862), and the optimal rate is determined (Fig. 9, 838). Please note that the examiner is interpreting the first and next time period as 512 beats times the number of AV "bins", the parameter as cardiac performance, and the metric as delta P.

7. In regards to claims 2 and 12, the therapy is repeated for the first rate if the therapy is not delivered for the predetermined portion of the first time period (Fig. 10, 870 to 872 to 862).

8. In regards to claims 3 and 13, the therapy is repeated for the second rate if the therapy is not delivered for a predetermined portion of the next time period (Fig. 10, 870 to 872 to 862).

9. In regards to claims 4 and 14, repeated delivery at the first rate and repeated delivery at the second rate is repeated a predetermined number of times (Fig. 10, 880 to 882 to 884 to 862).

10. In regards to claims 5 and 15, the parameter corresponds to a hemodynamic event (col. 10, line 6). The examiner is interpreting a heart wall acceleration as a hemodynamic event.

11. In regards to claims 7 and 17, the therapy is delivered at the first rate and second rate during a second time period different from the first and "delta P" metrics are generated (Fig. 10, 880 to 882 to 884 to 862).

12. In regards to claims 9 and 19, one of the first rate and second rate is applied as the current therapy based on the first metric or second metric being less than the other by a threshold (col. 20, line 35).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al. in view of Mehra et al. (6,185,495). Bornzin et al. disclose the essential features of the claimed invention except for expressly disclosing that a predetermined number of arrhythmia events are detected before delivering a new therapy. Mehra et al. teach of an implantable device that initiates a new therapy based on the detection of a predetermined number of arrhythmic events in a predetermined period (col. 13) to provide a therapy that is an improvement over the existing therapy or lack of therapy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bornzin et al.'s invention by initiating a new therapy based on the detection of a predetermined number of arrhythmic events in a predetermined period to provide a therapy that is an improvement over the existing therapy or lack of therapy.

16. Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al. in view of Valikai et al. (5,948,005). Bornzin et al. disclose the essential features of the claimed invention except for measuring arrhythmic events as the first and next parameters. Valikai et al. teach of creating histograms based on heart rate and arrhythmic events (in the form of the resulting paced events) to minimize arrhythmic events based on heart rate. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bornzin et al.'s

invention by optimizing with respect to arrhythmic events instead of cardiac performance to minimize arrhythmic events based on heart rate.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Other examples of pacemaker optimization strategies are provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571)272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK

10/4/05

GEORGE R. EVANISKO
PRIMARY EXAMINER

10/4/5